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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/923,304      | 08/06/2001  | Ruth Katz            | UTSC:658US/SLH      | 1430             |

7590 04/19/2002  
Steven L. Highlander  
FULBRIGHT & JAWORSKI L.L.P.  
600 CONGRESS AVENUE, SUITE 2400  
AUSTIN, TX 78701

EXAMINER

GOLDBERG, JEANINE ANNE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1634

DATE MAILED: 04/19/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/923,304

Applicant(s)

KATZ ET AL.

Examiner

Jeanine A Goldberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 8/6/01; 1/11/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-88 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-29, 57-66, 68-82, 84-88, drawn to method for identifying a subject at risk for development of cancer using a RPL14 gene probe, classified in class 435, subclass 6.
  - II. Claims 1-29, 57-66, 68-82, 84-88, drawn to method for identifying a subject at risk for development of cancer using a CD39L3 gene probe, classified in class 435, subclass 6.
  - III. Claims 1-29, 57-66, 68-82, 84-88, drawn to method for identifying a subject at risk for development of cancer using a PMGM gene probe, classified in class 435, subclass 6.
  - IV. Claims 1-29, 57-66, 68-82, 84-88, drawn to method for identifying a subject at risk for development of cancer using a GC20 gene probe, classified in class 435, subclass 6.
  - V. Claims 30-56, 67, 69-80, 83, 85-86, drawn to method for identifying a subject at risk for development of cancer using a 10q22 gene probe, classified in class 435, subclass 6.
2. The inventions are distinct, each from the other because of the following reasons:

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The inventions of Group I-V are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I uses RPL14 gene probe (SEQ ID NO: 1), Group II uses CD39L3 gene probes (SEQ ID NO: 3), Group III uses PMGM gene probes (SEQ ID NO: 5), Group IV uses GC20 gene probes (SEQ ID NO: 7) and Group V uses 10q22 probes. Each of these methods is directed to detection of different genes.

A search of one of the genes with respect to cancer risk would not be a coextensive search for each of the other genes and its association with cancer. A separate search would be required.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Should applicant traverse on the ground that the methods using the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

It is noted that numerous claims are found in more than one group. The claims will be examined to the extent that they apply to the elected subject matter. Upon indication of allowable claims, non-elected subject matter must be cancelled prior to allowance.

Therefore the methods are distinct over one another.

3. Because these inventions are distinct for the reasons given above and their divergent subject matter, restriction for examination purposes as indicated is proper.
4. A telephone call was made to Steven Highlander on March 28, 2002 to request an oral election to the above restriction requirement, but did not result in an election being made.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg  
April 8, 2002

  
W. Gary Jones  
Supervisory Patent Examiner  
Technology Center 1600